PCT/NZ03/00152

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Intellectual Property Office of New Zealand
Te Pou Rāhui Hanga Hou

CERTIFICATE

This certificate is issued in support of an application for Patent registration in a country outside New Zealand pursuant to the Patents Act 1953 and the Regulations thereunder.

I hereby certify that annexed is a true copy of the Provisional Specification as filed on 12 July 2002 with an application for Letters Patent number 520167 made by FISHER & PAYKEL HEALTHCARE LIMITED.

Dated 31 July 2003.

PRIORITY DOCUMENT
SUBMITTED OR TRANSMITTED IN COMPLIANCE WITH RULE 17.1(a) OR (b)

Neville Harris
Commissioner of Patents

NEW ZEALAND

PATENTS ACT, 1953

PROVISIONAL SPECIFICATION

Breathing Assistance Apparatus

We, FISHER & PAYKEL HEALTHCARE LIMITED, a company duly incorporated under the laws of New Zealand, of 15 Maurice Paykel Place, East Tamaki, Auckland, New Zealand, do hereby declare this invention to be described in the following statement:

FIELD OF INVENTION

This invention relates to patient interfaces particularly though not solely for use in delivering CPAP therapy to patients suffering from obstructive sleep apnoea (OSA).

BACKGROUND OF THE INVENTION

In the art of respiration devices, there are well known variety of respiratory masks which cover the nose and/or mouth of a human user in order to provide a continuous seal around the nasal and/or oral areas of the face such that gas may be provided at positive pressure within the mask for consumption by the user. The uses for such masks range from high altitude breathing (i.e., aviation applications) to mining and fire fighting applications, to various medical diagnostic and therapeutic applications.

One requisite of such respiratory masks has been that they provide an effective seal against the user's face to prevent leakage of the gas being supplied. Commonly, in prior mask configurations, a good mask-to-face seal has been attained in many instances only with considerable discomfort for the user. This problem is most crucial in those applications, especially medical applications, which require the user to wear such a mask continuously for hours or perhaps even days. In such situations, the user will not tolerate the mask for long durations and optimum therapeutic or diagnostic objectives thus will not be achieved, or will be achieved with great difficulty and considerable user discomfort.

US Patent No. 5,243,971 and US Patent No. 6,112,746 are examples of prior art attempts to improve the mask system US Patent No. 5,570,689 and PCT publication No. WO 00/78384 are examples of attempts to improve the forehead rest.

Where such masks are used in respiratory therapy, in particular treatment of obstructive sleep apnea (OSA) using continuance positive airway pressure (CPAP) therapy, there is generally provided in the art a vent for washout of the bias flow or expired gases to the atmosphere. Such a vent may be provided for example, as part

of the mask, or in the case of some respirators where a further conduit carries the expiratory gases, at the respirator. A further requisite of such masks is the washout of gas from the mask to ensure that carbon dioxide build up does not occur over the range of flow rates. In the typical flow rates in CPAP treatment, usually between 4cm H_2O to 20cm H_2O, prior art attempts at such vents have resulted in excessive noise causing irritation to the user and any bed partners.

Various approaches have been developed in the prior art to attempt to reduce the noise when CPAP therapy is provided. For example, in PCT Patent Application No. WO98/34665 it has been proposed that the vent include a resilient plug with rounded edge apertures to reproduce noise. However, this is not entirely effective in eliminating the extra noise created by a vent at the mask.

In common with all attempts to improve the fit, sealing and user comfort is the need to avoid a concentrated flow of air at any portion of the respiratory tracts. In particular with oral masks or mouthpieces it is a disadvantage of prior art devices that the oral cavity may become overly dehydrated by use of the device, causing irritation and possible later complications.

SUMMARY OF THE INVENTION

It is an object of the present invention to attempt to provide a patient interface which goes some way to overcoming the abovementioned disadvantages in the prior art or which will at least provide the industry with a useful choice.

Accordingly in a first aspect the present invention may be broadly said to consist in a sealing interface for use with delivery of respiratory gases to a user comprising

an inner sealing member

an outer sealing member

wherein said inner said sealing member and outer sealing member are adapted to seal around the facial contours of said user thereby providing a sealed fluid communication to the respiratory tract of said user, and

wherein said inner sealing and said outer sealing member are continuously in contact with each other around the facial contour contacting portions respectively.

Preferably said inner sealing member and said outer sealing member are continuously in contact both in use and when not in use around the facial contour contacting region.

Preferably said inner sealing member including a cheek region of said facial contour contacting region wherein said cheek region is concaved to accommodate the cartilages extending away from the middle of the nose of a user.

Preferably said facial contour contacting portion comprising a nasal bridge region whereby said nasal bridge region is tapered away from said user with respect to the remainder of said facial contour contacting portion.

Preferably said nasal bridge region comprising a inner region a middle region and a outer region whereby in use said inner region is most proximate said user.

Preferably said inner said inner portion said middle portion and said outer portion comprise dead space.

Alternatively said inner portion comprises a flexible resilient member and said middle region and said outer region comprise dead space.

In a still further alternative said inner region and said outer region comprise a resilient deformable material and said middle region comprises dead space.

Preferably said inner sealing member is adapted to follow said concave portion in said cheek region.

Alternatively said inner sealing member is adapted to contact said cheek region only when in use.

In a second aspect the present invention may be boardly said to consist in a patient interface for delivering respiratory gases to a user characterised in that comprising a sealing interface as described in any of the above clauses.

This invention may also be said broadly to consist in the parts, elements and features referred to or indicated in the specification of the application, individually or collectively, and any or all combinations of any two or more of said parts, elements or features, and where specific integers are mentioned herein which have known equivalents in the art to which this invention relates, such known equivalents are deemed to be incorporated herein as if individually set forth.

The invention consists in the foregoing and also envisages constructions of which the following gives examples.

BRIEF DESCRIPTION OF THE DRAWINGS

One preferred form of the present invention will now be described with reference to the accompanying drawings in which;

Figure 1 is a block diagram of a humidified continuous positive airway pressure (system) as might be used in conjunction with the present invention,

Figure 2 is an illustration of the nasal mask in use according to the preferred embodiment of the present invention,

Figure 3 shows a perspective view of the mask with cushion,

Figure 4 is a cutaway view of the mask showing the cushion,

Figure 5 is a cutaway view of the periphery of the outer membrane,

Figure 6 is a cutaway view of the periphery of the mask body portion,

Figure 7 shows a make with the forehead rest on a user, and

Figure 8 shows the forehead rest in isolation.

Figure 9 shows a cross section of second preferred embodiment of the mask cushion

Figure 10 shows perspective view of a foam member of the second preferred embodiment of the mask cushion

Figure 11 shows a cross section of the third preferred embodiment of the mask cushion

Figure 12A shows a perspective view of the inner foam member of the third preferred embodiment of the mask cushion

Figure 12B shows a plan view of the inner foam member of the third preferred embodiment of the mask cushion

Figure 13 shows a cross section of a fourth preferred embodiment of the mask cushion

Figure 14 shows a perspective view of the inner foam member according to a fifth preferred embodiment of the mask cushion.

The present invention provides improvements in the delivery of CPAP therapy. In particular a patient interface is described which is quieter for the user to wear and reduces the side leakage as compared with the prior art. It will be appreciated that the patient interface as described in the preferred embodiment of the present invention can be used in respiratory care generally or with a ventilator but will now be described below with reference to use in a humidified CPAP system. It will also be appreciated that the present invention can be applied to any form of patient interface including, but not limited to, nasal masks, oral masks and mouthpieces.

With reference to Figure 1 a humidified Continuous Positive Airway Pressure (CPAP) system is shown in which a patient 1 is receiving humidified and pressurised gases through a patient interface 2 connected to a humidified gases transportation pathway or inspiratory conduit 3. It should be understood that delivery systems could also be VPAP (Variable Positive Airway Pressure) and BiPAP (Bi-level Positive Airway Pressure) or numerous other forms of respiratory therapy. Inspiratory conduit 3 is connected to the outlet 4 of a humidification chamber 5 which contains a volume of water 6. Inspiratory conduit 3 may contain heating means or heater wires (not shown) which heat the walls of the conduit to reduce condensation of humidified gases within the conduit. Humidification chamber 6 is preferably formed from a plastics material and may have a highly heat conductive base (for example an aluminium base) which is in direct contact with a heater plate 7 of humidifier 8. Humidifier 8 is provided with control means or electronic controller 9 which may comprise a microprocessor based controller executing computer software commands stored in associated memory.

Controller 9 receives input from sources such as user input means or dial 10 through which a user of the device may, for example, set a predetermined required value (preset value) of humidity or temperature of the gases supplied to patient 1. The controller may also receive input from other sources, for example temperature and/or flow velocity sensors 11 and 12 through connector 13 and heater plate temperature sensor 14. In response to the user set humidity or temperature value

input via dial 10 and the other inputs, controller 9 determines when (or to what level) to energise heater plate 7 to heat the water 6 within humidification chamber 5. As the volume of water 6 within humidification chamber 5 is heated, water vapour begins to fill the volume of the chamber above the water's surface and is passed out of the humidification chamber 5 outlet 4 with the flow of gases (for example air) provided from a gases supply means or blower 15 which enters the chamber through inlet 16. Exhaled gases from the patient's mouth are passed directly to ambient surroundings in Figure 1.

Blower 15 is provided with variable pressure regulating means or variable speed fan 21 which draws air or other gases through blower inlet 17. The speed of variable speed fan 21 is controlled by electronic controller 18 (or alternatively the function of controller 18 could carried out by controller 9) in response to inputs from controller 9 and a user set predetermined required value (preset value) of pressure or fan speed via dial 19.

Nasal Mask

According to a first embodiment of the present invention the patient interface is shown in Figure 2 as a nasal mask. The mask includes a hollow body 102 with an inlet 103 connected to the inspiratory conduit 3. The mask 2 is positioned around the nose of the user 1 with the headgear 108 secured around the back of the head of the patient 1. The restraining force from the headgear 108 on the hollow body 102 and the forehead rest 106 ensures enough compressive force on the mask cushion 104, to provide an effective seal against the patient's face.

The hollow body 102 is constructed of a relatively inflexible material for example, polycarbonate plastic. Such a material would provide the requisite rigidity as well as being transparent and a relatively good insulator. The expiratory gases can be expelled through a valve (not shown) in the mask, a further expiratory conduit (not shown), or any other such method as is known in the art.

Mask Cushion

Referring now to Figures 3 and 4 in particular, the mask cushion 1104 is provided around the periphery of the nasal mask 1102 to provide an effective seal

onto the face of the user to prevent leakage. The mask cushion 1104 is shaped to approximately follow the contours of a patient's face. The mask cushion 104 will deform when pressure is applied by the headgear 1108 to adapt to the individual contours of any particular user. In particular, there is an indented section 1150 intended to fit over the bridge of the user's nose as well as a less indented section 1152 to seal around the section beneath the nose and above the upper lip.

In Figure 4 we see that the mask cushion 1104 is composed of a inner foam cushion 1110 covered by an outer sealing sheath 1112. The inner cushion 1110 is constructed of a resilient material for example polyurethane foam, to distribute the pressure evenly along the seal around the user's face. The inner cushion 1110 is located around the outer periphery 1114 of the open face 1116 of the hollow body 1102. Similarly the outer sheath 1112 may be commonly attached at its base 1113 to the periphery 1114 and loosely covers over the top of the inner cushion 1110.

In the preferred embodiment shown in Figures 4-6 the bottom of the inner cushion 1110 fits into a generally triangular cavity 1154 in the hollow body 1102. The cavity 1154 is formed from a flange 1156 running mid-way around the interior of the hollow body.

The outer sheath 1112 fits in place over the cushion 1110, holding it in place. The sheath 1112 is secured by a snap-fit to the periphery 1114 of the hollow body. In Figures 5-6 the periphery 1114 is shown including an outer bead 1158. The sheath 1112 includes a matching bead 1159, whereby once stretched around the periphery, the two beads engage to hold the sheath in place.

Referring now to Figures 9 and 10 a second preferred embodiment to the mask cushion is depicted. In the second embodiment the inner foam cushion 2000 includes a raised bridge 2002 in the nasal bridge region. Thus the notch in the contacting portion is less pronounced than proceeding embodiments, however as the raised bridge 2002 is unsupported it is much more flexible and results in less pressure on the nasal bridge of the user. The outer sheath 2004 contacts the foam cushion 2000 throughout the raised bridge 2002.

Referring particularly to Figure 10 the foam cushion 2000 includes a check contour 2006 to follow the cartilage extending from he middle of the nose, and a contoured lip sealing portion 2008 to seal between the base of the nose and the upper lip

Referring now to Figures 11 and 12 a third preferred embodiment of the mask cushion is depicted. In this case the foam cushion 2010 tapers down 2012 towards the nasal bridge region 2014. For a short portion either side of the nasal bridge region 2014 the foam cushion 2010 is absent, forming a semi annular form in plan view as seen in Figure 12B.

Referring to Figures 13 a fourth preferred embodiment of the mask cushion is depicted. The outer sheath 2020 is adapted to contact the foam cushion 2022 all around, including in the nasal bridge region 2024, and the check contour 2026.

Figure 14 illustrates a fifth preferred embodiment of the foam cushion 2030. In the nasal bridge region 2032 the foam cushion included a lower bridge 2034 and upper bridge 2036. Due to the gap the upper bridge is unsupported to reduce pressure on the users nasal bridge, but the lower rim 2038 of the foam cushion 2030 is continuous, which aids installation.

Forehead Rest

In the preferred embodiment of the present invention the nasal mask 2102 includes a hinged forehead rest 2106 (seen in Figures 7 and 8). The attachment of the forehead rest 2106 to the hollow body 2102 effectively allows the forehead rest 2106 to move freely in proximity to the user but with no lateral movement.

In one form shown in Figure 8, pins 2130 are provided mounted on a base 2132 attached to the hollow body 2102. These pins 2130 are co-axial within cylinders 2131 mounted on a bridge member 2136.

At the top end 2142 (around the user's forehead) of the bridge member 2136 harnessing slots 2138 are provided which allow straps from the headgear to be inserted to secure the mask to the headgear. For the user's comfort one or more resilient cushions 2140 are provided underneath the top end 2142 of the bridge member 2136, which rest on the forehead of the user. The cushion 2140 might be

constructed of silicon or any foam materials as is known in the art for providing cushioning.

For example the forehead rest 2106 described previously may include a weakened section 2130 at its base 2132 which allows the joining member 2136 to pivot from the hollow body 2102. The bridge member extends up to the forehead of the user. In a further alternative the mask may include a vertical upwardly extending inlet. In this case the member 2136 is hinged at its base 2132 to either side of the inlet passage. Again the member would then extend to the forehead. Alternatively any well-known form of hinge can be used to provide the pivoting action.

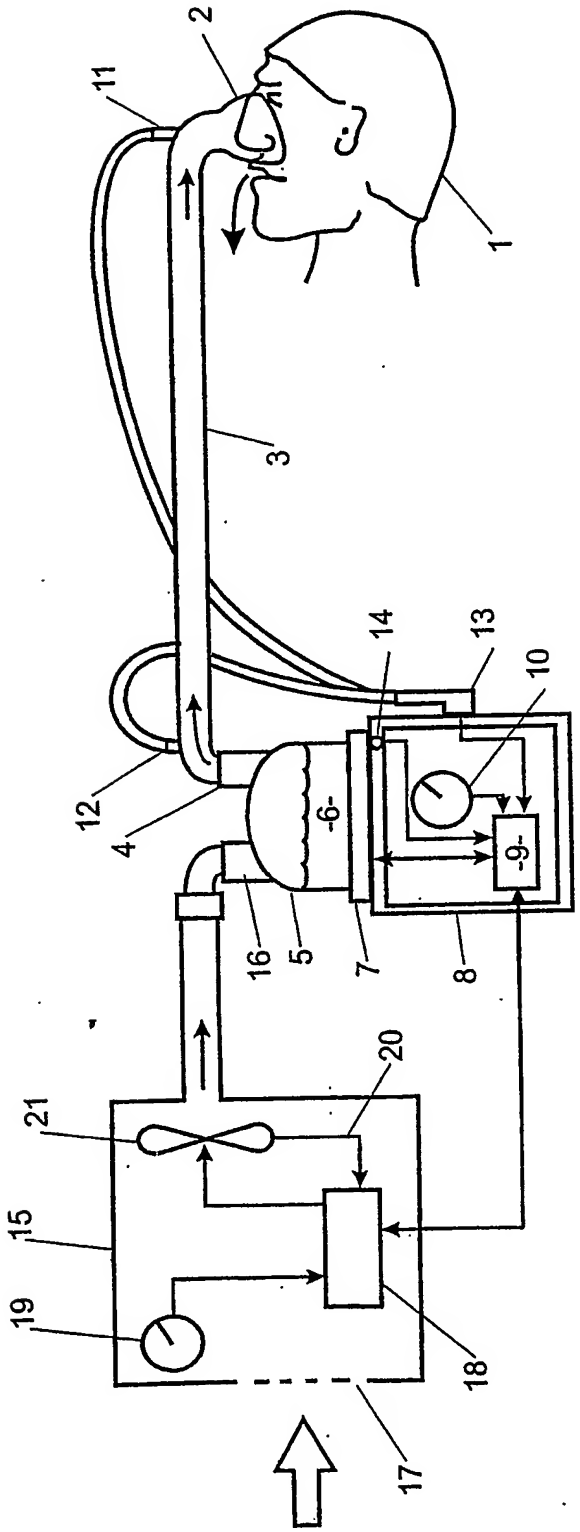

FIGURE 1

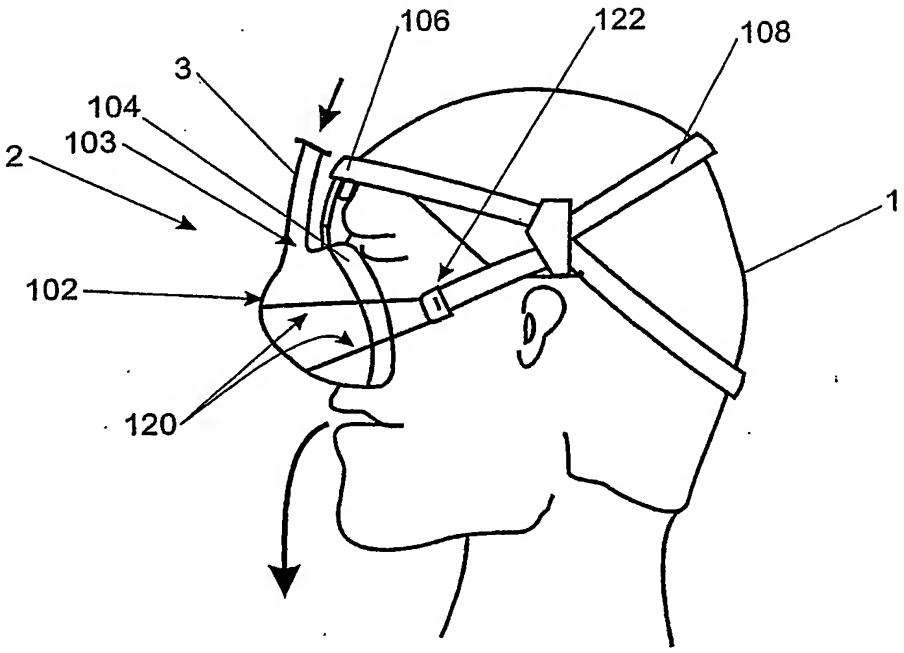

FIGURE 2

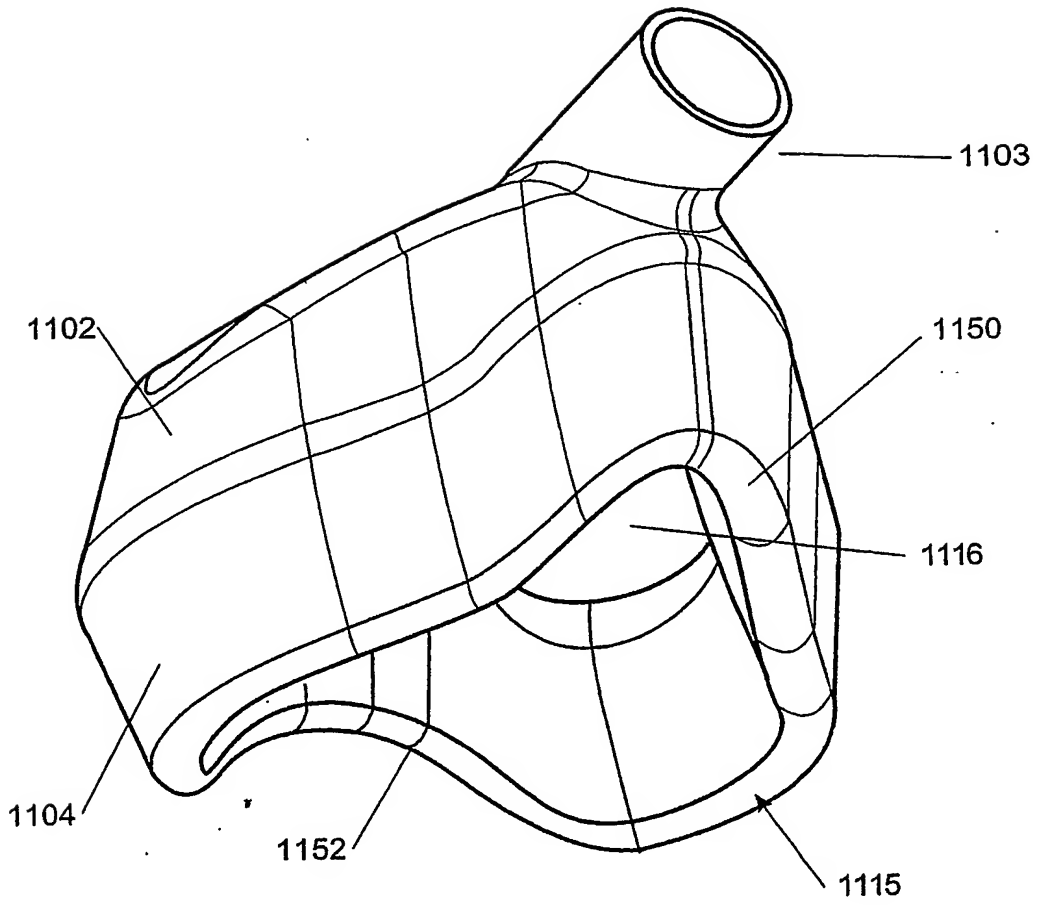

FIGURE 3

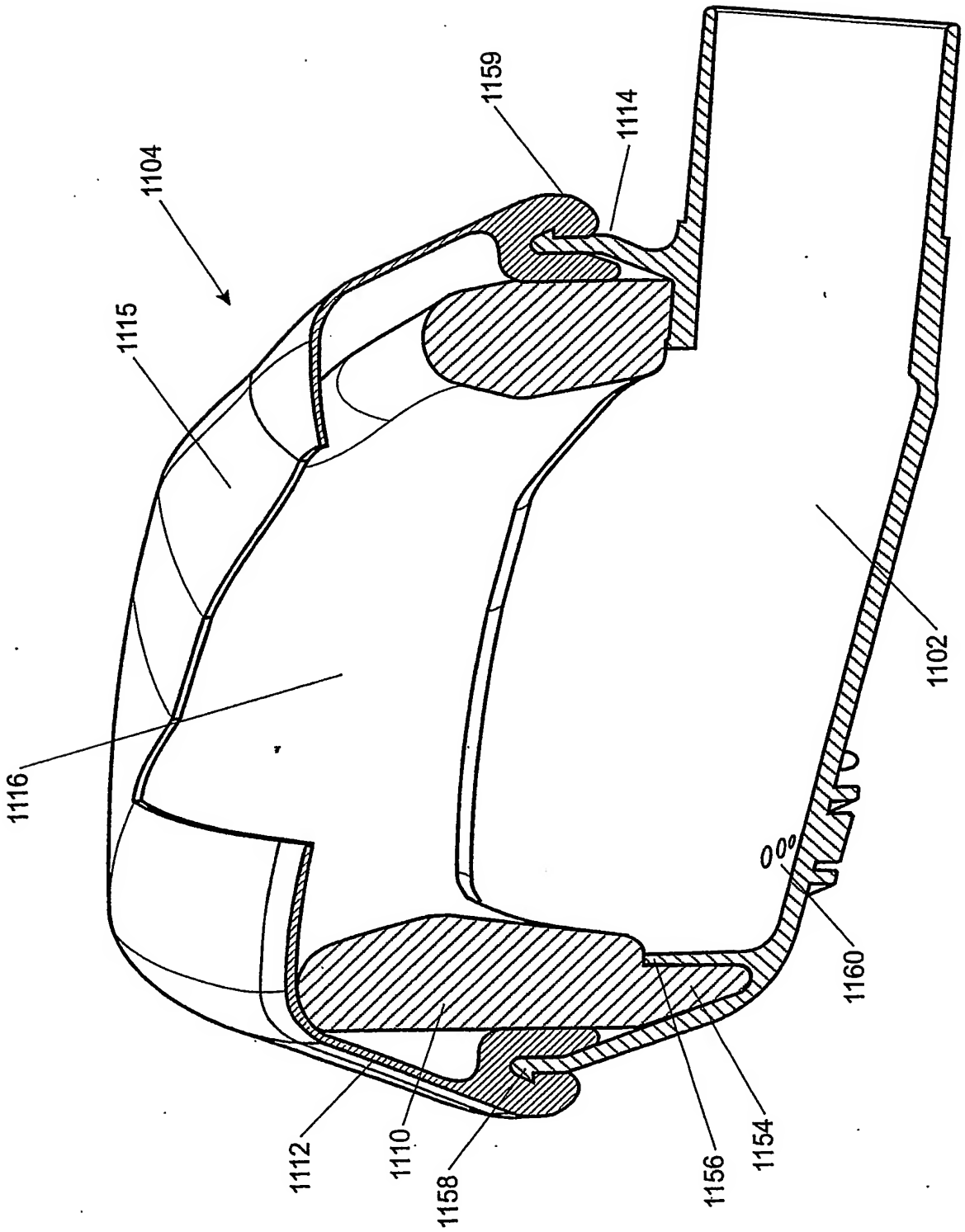
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FIGURE 4

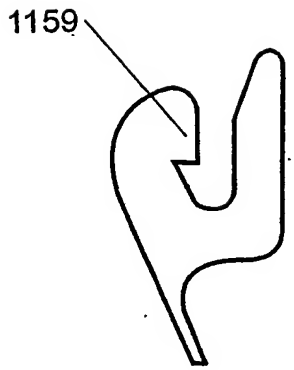

FIGURE 5

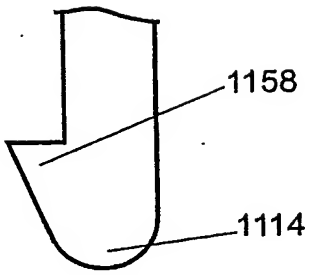

FIGURE 6

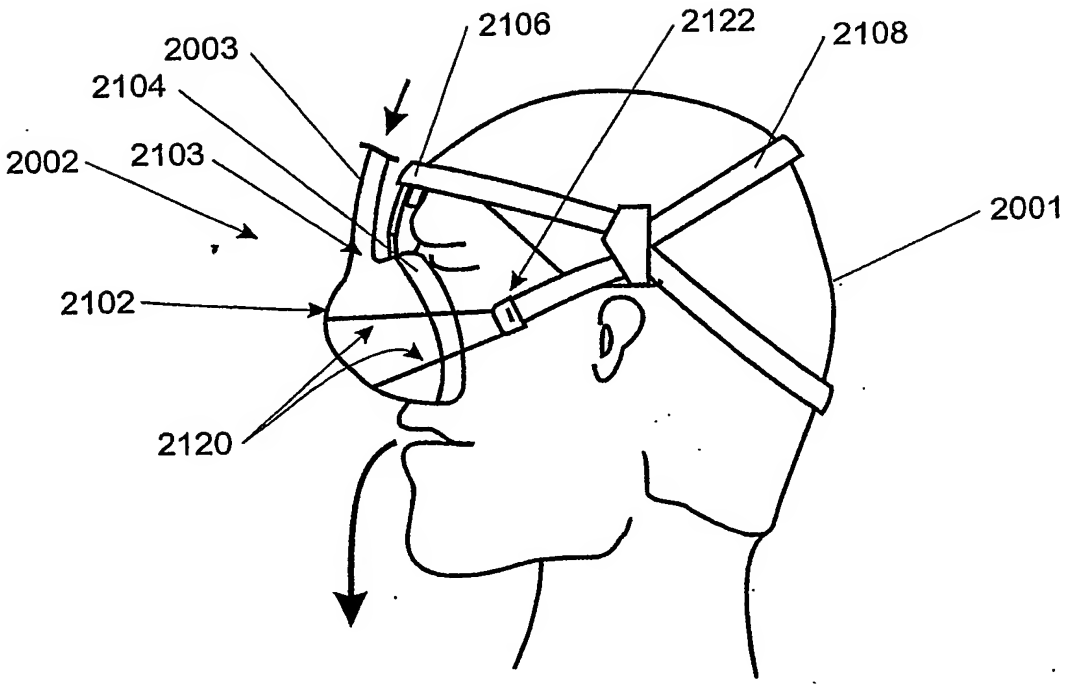

FIGURE 7

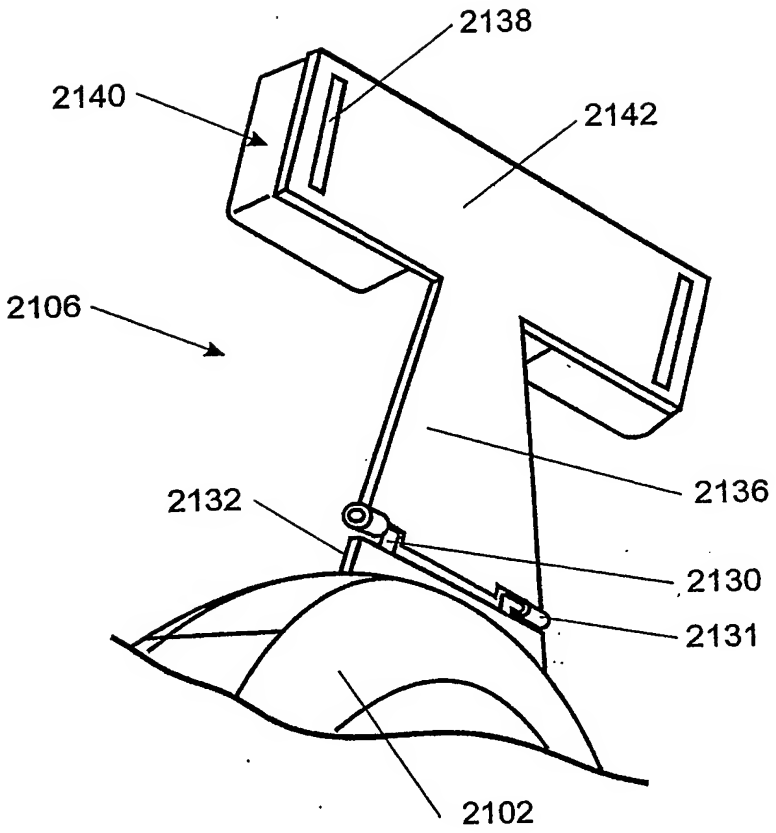

FIGURE 8

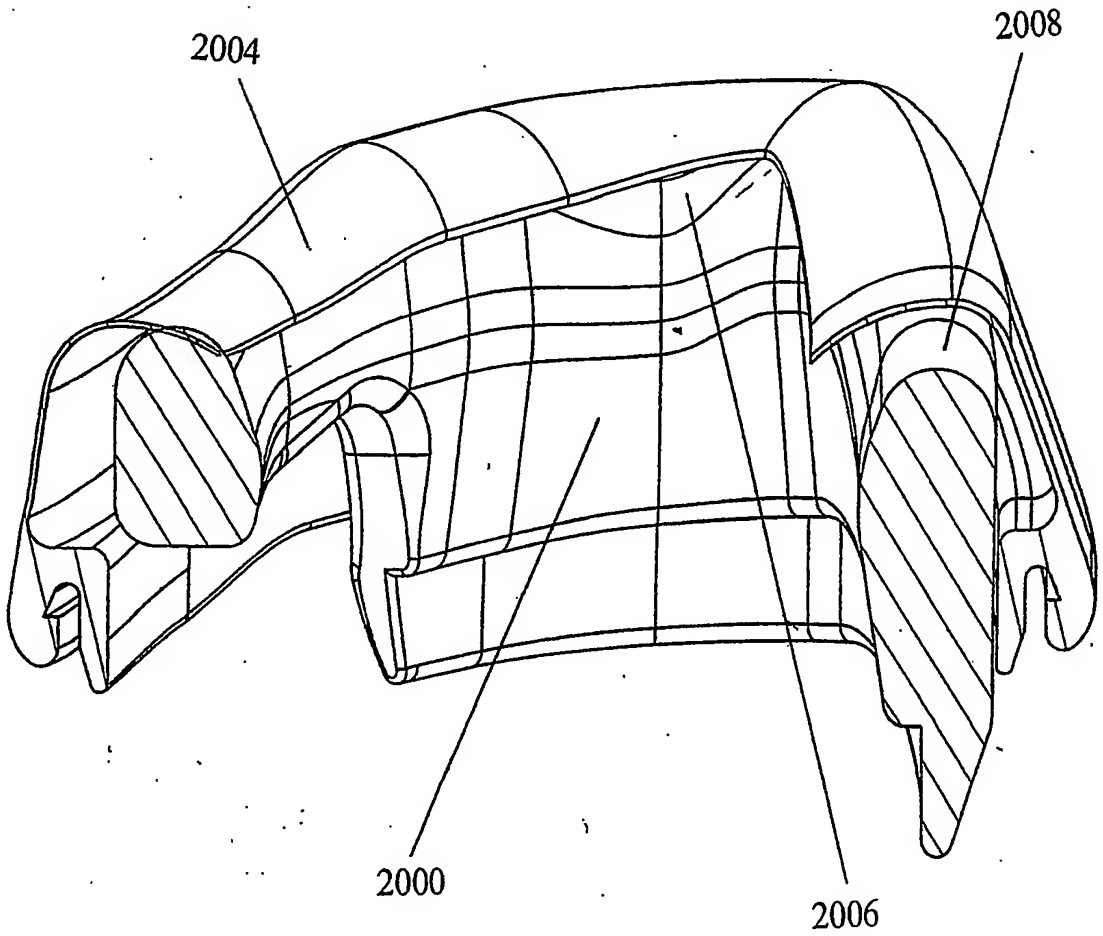

FIGURE 9

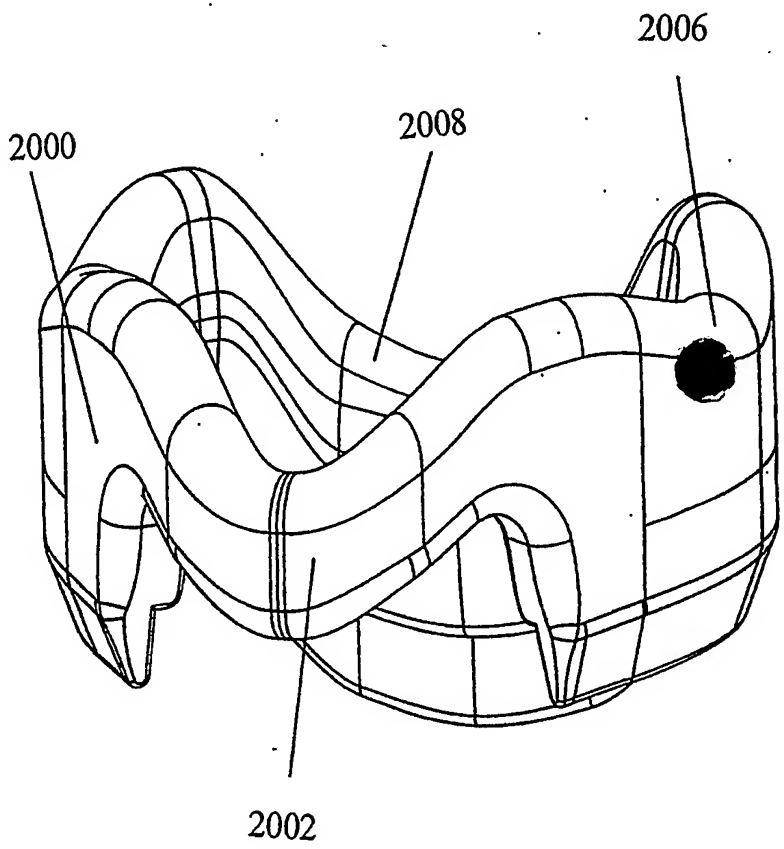

FIGURE 10

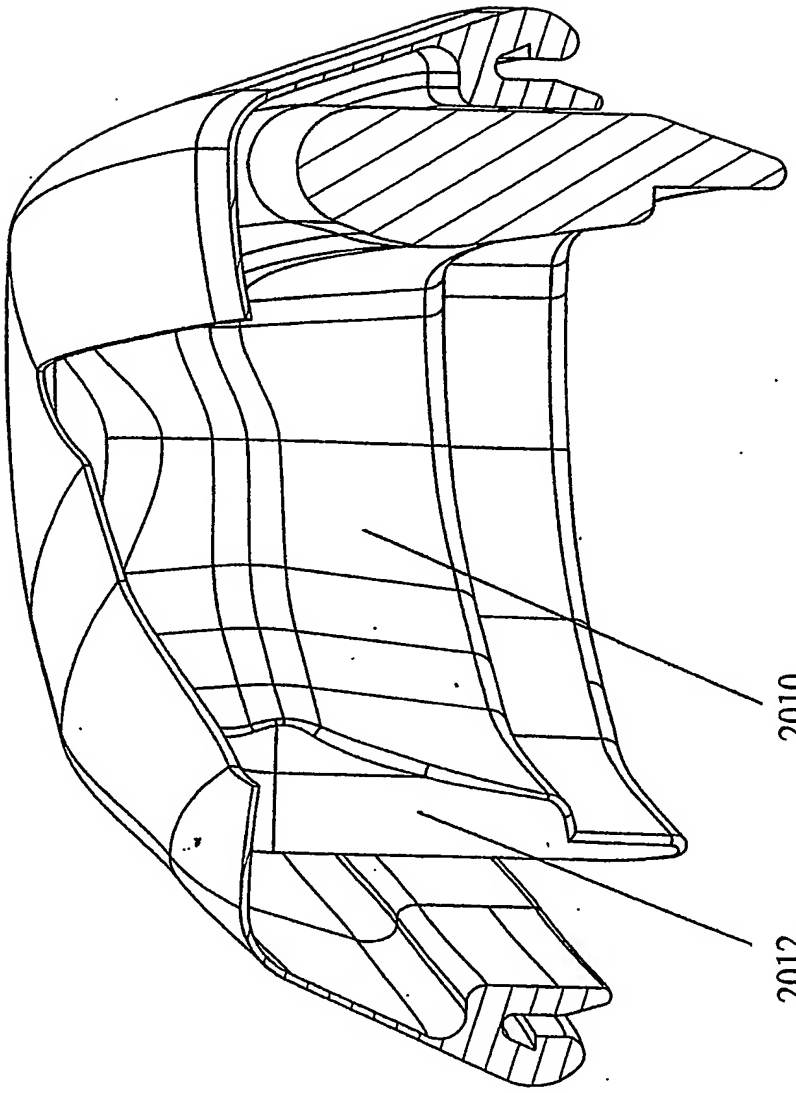

FIGURE 11

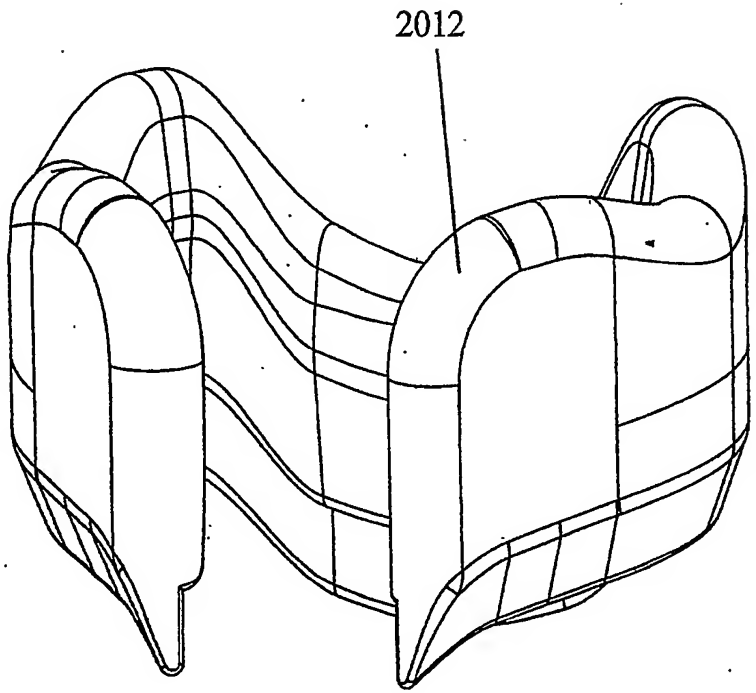

FIGURE 12A

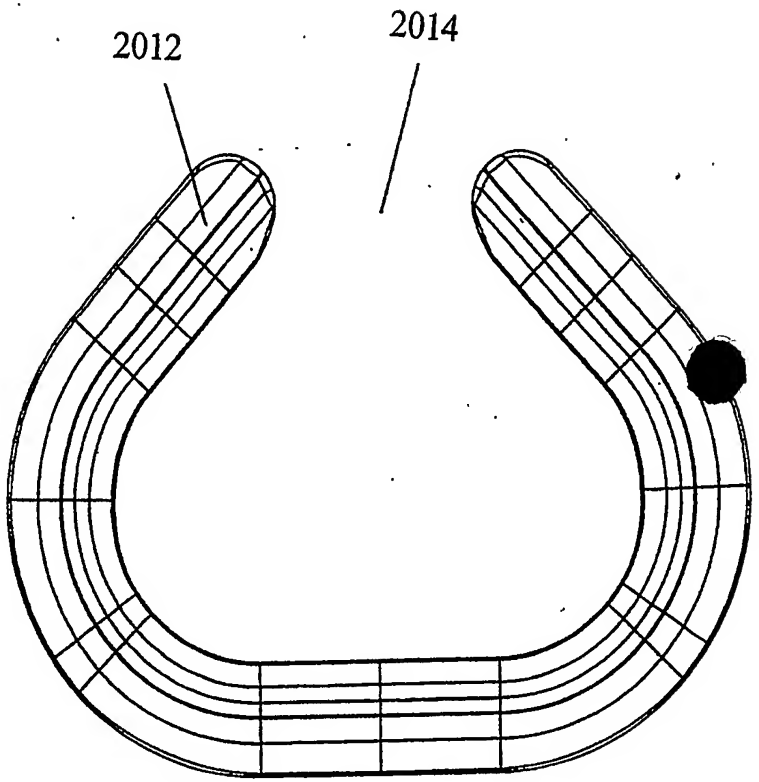

FIGURE 12B

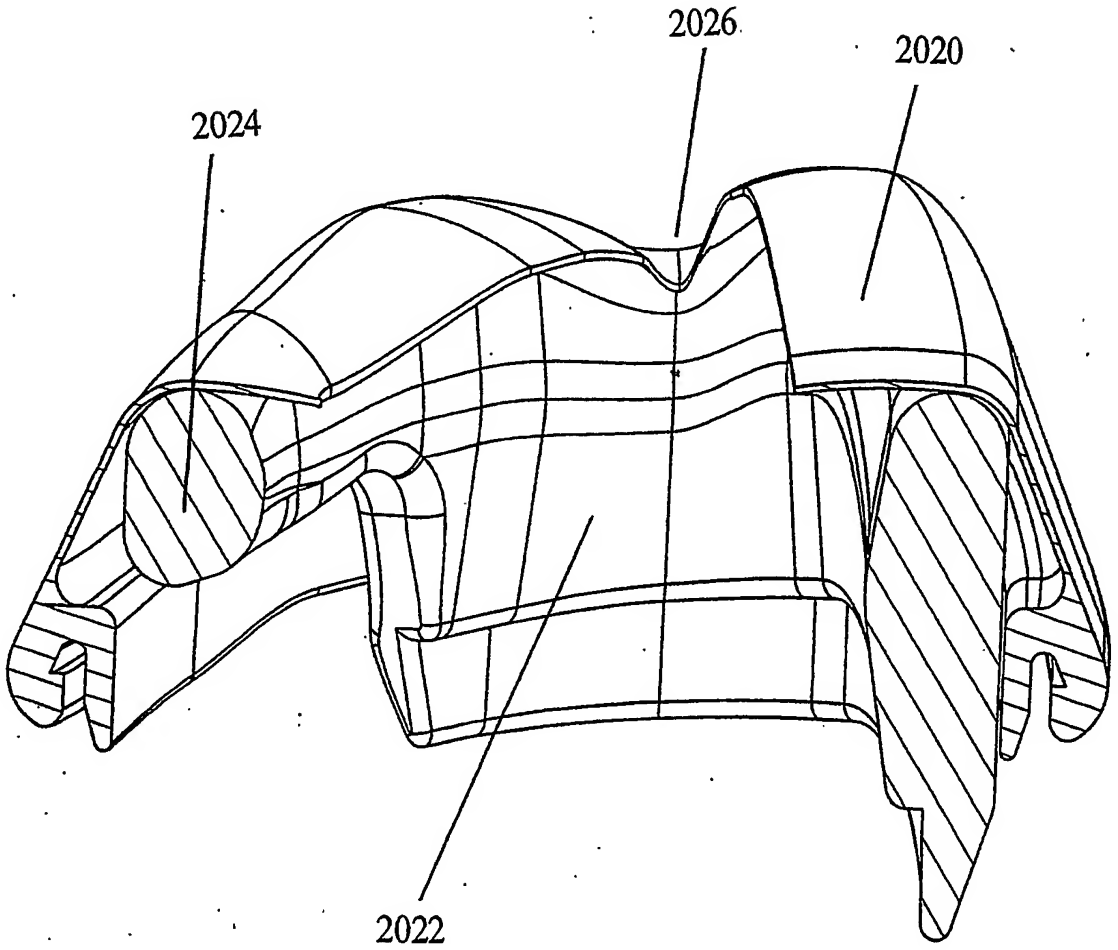

FIGURE 13

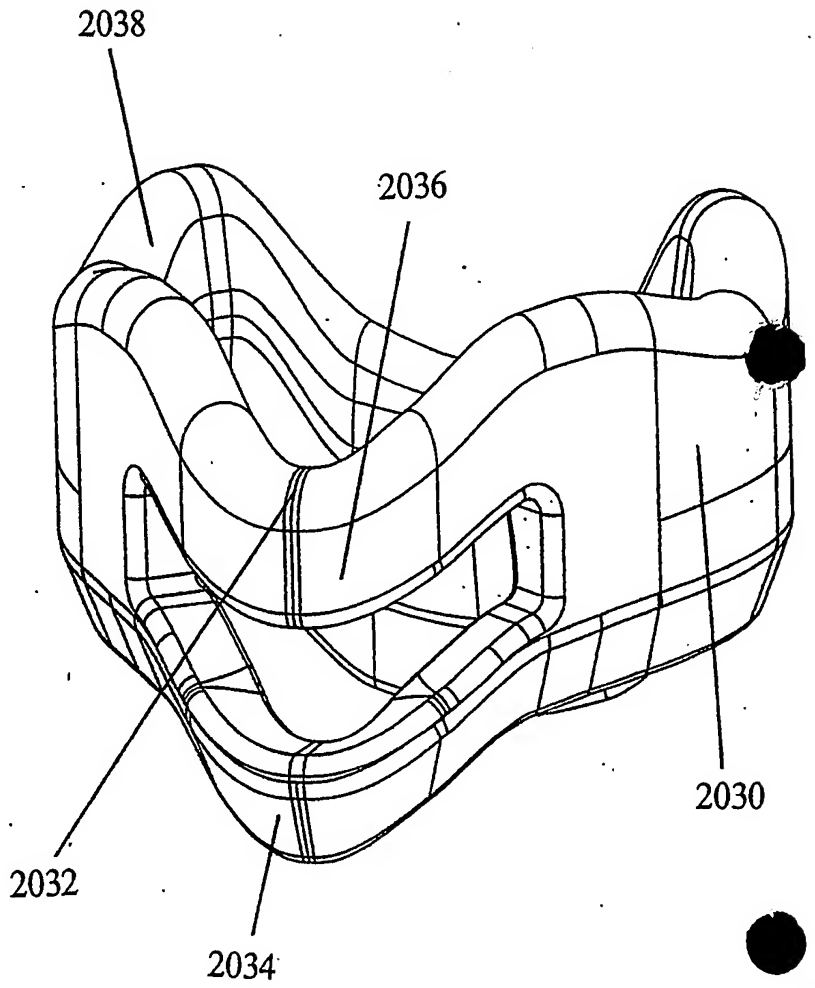

FIGURE 14